AUG 2 9 2001

K003555

Solo-*SAFE*™ Releasable 510(k) Summary

Submitter of the 510(k)

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Regulatory Consultant:

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Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, Safety and Effectiveness information is enclosed for the following device:

1. **Trade/Proprietary Name:**
   Solo-Safe™ Safety Syringe
   Size – 3cc

2. **Predicate Device:** BD Safety-Lok K920321 and K924072

3. **Common/Usual Name:**
   Safety Syringe, Hypodermic Syringe, Piston Syringe with Safety Mechanism

4. **Classification Name:**
   Piston Syringe with integral needle

5. **Classification:**
   Class II per 21 CFR 880.5860

6. **Product Code:**
   MEG– Anti-stick Syringe

7. **Classification Panel:**
   Panel 80 (General Hospital Use)

8. **Predicate Device Information:**
   A claim of substantial equivalence is made to: BD Safe-Lok K920321 and K924072

Device Description
The Solo-*SAFE*™ Syringe is a piston syringe with integral needle combined with a sharps injury prevention mechanism. The Solo-*SAFE*™ Syringe is a sterile, non-toxic, non-pyrogenic, retractable syringe designed to provide a safe and reliable method for intramuscular injection of drugs and/or fluids while helping to provide a protection from accidental needlestick. The injury prevention mechanism allows the user to actively pull the contaminated needle back into the barrel of the syringe after use. The user accomplishes this by pulling back on the plunger which has connected to the Solo-*SAFE*™ needle after being fully depressed. By pulling back on the plunger the user is able to retract the Solo-*SAFE*™ needle within the barrel of the syringe.

Substantial Equivalence
The following tables show the basis for substantial equivalence:

	Predicate Device (K920321)	**Submission Device**	**SE**
	BD Safety Lok 3cc Syringe	**Solo- *SAFE* 3cc Syringe**	
Indications for Use	Indicated for IM injection	Indicated for IM injection	YES
Safety Feature	Active safety feature, manually activated by user	Active safety feature, manually activated by user	YES
Sites of Use/Users	Hospitals, clinics, laboratories	Hospitals, clinics, laboratories	YES
Syringe Type	Plunger, antistick with hypodermic needle	Plunger, antistick with hypodermic needle	YES
Volume	3cc	3cc	YES
Available Needle Ga	25G x 5/8 inches 23G x 1 inches 22G x 1 ½ inches 22G x 1 inch 21G x 1 ½ inches	21G x 1 ½ inches	YES
Materials	Polypropylene, rubber, stainless steel, adhesive, lubricant	Polypropylene, rubber, stainless steel, lubricant, adhesive	YES

Statement of Intended Use
The Solo-SAFE Syringe is indicated for use in the administration of an intramuscular (IM) injection.

The Spectrum 3cc Solo-SAFE Syringe primary intended use is for injection of medications and fluids into the patient. The Solo-SAFE has an active safety feature that is safe and effective for intramuscular (IM) injections only. Its secondary intended use is the safety feature of the device which helps prevent sharps injuries when using the device for its primary intended use. Solo-SAFE is a sterile, single use, disposable syringe.

Performance Data
Design verification testing was conducted to confirm that the device met functional and specifications. Also a simulated use study with healthcare professionals demonstrated that the Solo-*SAFE* syringe was substantially equivalent in performance to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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C/O Mr. Ian McDougall
Regulatory Consultant
Spectrum Biotech, Incorporated
821 East 17th Street
North Vancouver, British Columbia
V7L 2X2

Re: K003555
Trade/Device Name: Solo-Safe Safety Syringe, Size-3CC
Regulation Number: 880.5860
Regulatory Class: II
Product Code: MEG
Dated: August 11, 2001
Received: August 16, 2001

Dear Mr. McDougall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

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Patricia Cercenie

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003555